Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL QUALITY MEASURES CLEARINGHOUSE

General

Title

Oncology: percentage of patients, regardless of age, with a diagnosis of breast, rectal, pancreatic or lung cancer receiving 3D conformal radiation therapy who had documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues.

Source(s)

American Society for Radiation Oncology (ASTRO). Oncology: radiation dose limits to normal tissues. Fairfax (VA): American Society for Radiation Oncology (ASTRO); 2015 Nov 17. 7 p.

Measure Domain

Primary Measure Domain

Clinical Quality Measures: Process

Secondary Measure Domain

Does not apply to this measure

Brief Abstract

Description

This measure is used to assess the percentage of patients, regardless of age, with a diagnosis of breast, rectal, pancreatic or lung cancer receiving 3D conformal radiation therapy who had documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues.

Rationale

Identifying radiation dose limits to normal tissues is an important step in the process of care for patients receiving radiation therapy treatments. Although no specific data is available, in its practice accreditation reviews, the American College of Radiation Oncology has found that radiation dose limits to normal tissues are included in the patient chart less frequently than reviewers expected. While dose constraint

specification is an integral part of intensity-modulated radiation therapy (IMRT), it is not required for 3D conformal radiation therapy. Patients treated with 3D conformal radiation therapy are often subjected to dose levels that exceed normal tissue tolerance, and precise specification of maximum doses to be received by normal tissues represent both an intellectual process for the physician during radiation treatment planning, and a fail-safe point for the treating therapists. In most circumstances where facilities require specification of radiation dose limits to normal tissues prior to initiation of therapy, policies and procedures exist that prohibit exceeding those limits in the absence of written physician approval.

Clinical Recommendation Statements

Breast Cancer

Whole Breast Radiation: Target definition includes the majority of the breast tissue, and is best done by both clinical assessment and computed tomography (CT)-based treatment planning. A uniform dose distribution and minimal normal tissue toxicity are the goals and can be accomplished using compensators such as wedges, forward planning using segments, IMRT, respiratory gating, or prone positioning (National Comprehensive Cancer Network [NCCN], 2014).

Chest Wall Radiation (including breast reconstruction)

The target includes the ipsilateral chest wall, mastectomy scar, and drain sites where possible. Depending on whether the patient has been reconstructed or not, several techniques using photons and/or electrons are appropriate. CT-based treatment planning is encouraged in order to identify lung and heart volumes, and minimize exposure of these organs. Special consideration should be given to the use of bolus material when photon fields are used, to ensure the skin dose is adequate (NCCN, 2014).

Rectal Cancer

Radiation therapy fields should include the tumor or tumor bed, with a 2-5 cm margin, the presacral nodes, and the internal iliac nodes. The external iliac nodes should also be included for T4 tumors involving anterior structures.

Multiple radiation therapy fields should be used (generally a 3- or 4-field technique). Positioning and other techniques to minimize the volume of small bowel in the fields should be encouraged (NCCN, 2016).

Pancreatic Adenocarcinoma

It is imperative to evaluate the dose volume histogram (DVH) of the planning target volume (PTV) and critical normal structures such as liver, kidneys, spinal cord, liver and bowel. While these limits are empirical they differ based on dose per fraction, total dose delivered, and disease status (adjuvant vs. unresectable). Studies have shown that the tolerability of radiation is largely dependent on PTV size/elective nodal irradiation, types of concurrent systemic/ targeted therapy, and whether conformal (3-D, IMRT, stereotactic body radiation therapy [SBRT]) vs. conventional radiation is used (NCCN, "Pancreatic adenocarcinoma," 2012).

Non-Small Cell Lung Cancer

It is essential to evaluate the DVH of critical structures and to limit the doses to the spinal cord, lungs, heart, esophagus, and brachial plexus to minimize normal tissue toxicity. These limits are mainly empirical. For patients receiving postoperative radiation therapy (RT), more strict DVH parameters should be considered for lung (NCCN, "Non-small cell lung cancer," 2012).

Small Cell Lung Cancer

Normal tissue doses will be dependent on tumor size and location (NCCN, "Small cell lung cancer," 2012).

Evidence for Rationale

American Society for Radiation Oncology (ASTRO). Oncology: radiation dose limits to normal tissues. Fairfax (VA): American Society for Radiation Oncology (ASTRO); 2015 Nov 17. 7 p.

National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: breast cancer. Version 1. Fort Washington (PA): National Comprehensive Cancer Network (NCCN); 2014.

National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: non-small cell lung cancer. Fort Washington (PA): National Comprehensive Cancer Network, Inc.; 2012 Apr 11.

National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: pancreatic adenocarcinoma. Fort Washington (PA): National Comprehensive Cancer Network, Inc.; 2012.

National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: rectal cancer. Version 1. Fort Washington (PA): National Comprehensive Cancer Network, Inc.; 2016.

National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: small cell lung cancer. Fort Washington (PA): National Comprehensive Cancer Network, Inc.; 2012 Jun 23.

Primary Health Components

Breast cancer; rectal cancer; pancreatic cancer; lung cancer; 3D conformal radiation therapy; radiation dose limits

Denominator Description

All patients, regardless of age, with a diagnosis of breast, rectal, pancreatic or lung cancer receiving 3D conformal radiation therapy (see the related "Denominator Inclusions/Exclusions" field)

Numerator Description

Patients who had documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues (see the related "Numerator Inclusions/Exclusions" field)

Evidence Supporting the Measure

Type of Evidence Supporting the Criterion of Quality for the Measure

A clinical practice guideline or other peer-reviewed synthesis of the clinical research evidence

One or more research studies published in a National Library of Medicine (NLM) indexed, peer-reviewed journal

Additional Information Supporting Need for the Measure

Unspecified

Extent of Measure Testing

Reliability

Data/Sample

Physician Consortium for Performance Improvement (PCPI) Testing Project

Five practice sites representing various types, locations and sizes were identified to participate in testing the PCPI/American Society of Clinical Oncology (ASCO)/American Society for Radiology and Oncology (ASTRO)-developed measures.

Site A: hospital, multi-practice sites in urban, rural and suburban settings; 21 physicians; average 9600 oncology/prostate cancer patient visits per month for medical doctor (MD)/nurse practitioner (NP) assessment, chemotherapy; submitted Physician Quality Reporting System (PQRS) claims for one measure and utilized a full-fledged electronic health record (EHR).
Site B: physician owned private practice, suburban setting; 4 physicians; average 48 oncology/prostate cancer patients seen per day; submitted PQRS claims for one measure and utilized paper medical records.
Site C: physician owned private practice, urban setting; 41 physicians; average 2500 oncology/prostate cancer patients seen per month; submitted PQRS claims for two measures and utilized a full-fledged EHR.
Site D: academic, suburban setting; 9 physicians; average 240 oncology/prostate cancer patients seen per month; submitted PQRS claims for one measure and utilized paper and EHR.
Site E: academic, urban setting; 14 physicians; average 250 oncology/prostate cancer patients seen per month; collected PQRS data on 3 measures and utilized a full-fledged EHR.
The measurement period (data collected from patients seen) was 1/1/2010 through 12/31/2010.
Chart abstraction was performed between 8/8/2011 and 11/3/2011.

Analytic Method

PCPI Testing Project

Data abstracted from patient records were used to calculate inter-rater reliability for the measure.
92 patient records were reviewed.

Data analysis included:

Percent agreement; and
Kappa statistic to adjust for chance agreement.

Testing Results

PCPI Testing Project

N, % Agreement, Kappa (95% Confidence Interval)
Overall Reliability: 92, 98.9%, 0.935 (0.809-1.000)
Denominator Reliability: 92, 100.0%, Kappa is noncalculable*
Numerator Reliability: 92, 98.9%, 0.935 (0.809-1.000)

This measure demonstrates almost perfect reliability, as shown in results from the above analysis.

*Kappa statistics cannot be calculated because of complete agreement. Confidence intervals cannot be calculated because to do so would involve dividing by zero which cannot be done.

Validity

Analytic Method

All PCPI performance measures are assessed for content validity by a panel of expert work group members during the development process. Additional input on the content validity of draft measures is obtained through a 30-day public comment period and by also soliciting comments from a panel of consumer, purchaser, and patient representatives convened by the PCPI specifically for this purpose. All

comments received are reviewed by the expert work group and the measures adjusted as needed. Other external review groups (e.g., focus groups) may be convened if there are any remaining concerns related to the content validity of the measures.

The expert panel was used to assess face validity of the measure. This panel consisted of 31 members, with representation from the following specialties: oncology, radiation oncology, surgical oncology, urology, gastroenterology, hematology, pathology, colon and rectal surgery, otolaryngology, and pain medicine.

The aforementioned panel was asked to rate their agreement with the following statement:

The scores obtained from the measure as specified will accurately differentiate quality across providers.

Scale 1-5, where 1=Strongly Disagree; 3=Neither Disagree nor Agree; 5=Strongly Agree

Testing Results

The results of the expert panel rating of the validity statement were as follows: N = 17; Mean rating = 4.18.

Percentage in the top two categories (4 and 5): 82.35%

Frequency Distribution of Ratings:

0
0
3
8
6

Evidence for Extent of Measure Testing

National Quality Forum (NQF) measure submission form: oncology: radiation dose limit to normal tissues. Washington (DC): National Quality Forum (NQF); 2011 Oct 3. 17 p.

State of Use of the Measure

State of Use

Current routine use

Current Use

not defined yet

Application of the Measure in its Current Use

Measurement Setting

Ambulatory/Office-based Care

Ambulatory Procedure/Imaging Center

Hospital Outpatient

Professionals Involved in Delivery of Health Services

not defined yet

Least Aggregated Level of Services Delivery Addressed

Individual Clinicians or Public Health Professionals

Statement of Acceptable Minimum Sample Size

Does not apply to this measure

Target Population Age

All patients, regardless of age

Target Population Gender

Either male or female

National Strategy for Quality Improvement in Health Care

National Quality Strategy Aim

Better Care

National Quality Strategy Priority

Prevention and Treatment of Leading Causes of Mortality

Institute of Medicine (IOM) National Health Care Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Data Collection for the Measure

Case Finding Period

Unspecified

Denominator Sampling Frame

Patients associated with provider

Denominator (Index) Event or Characteristic

Clinical Condition

Encounter

Therapeutic Intervention

Denominator Time Window

not defined yet

Denominator Inclusions/Exclusions

Inclusions
All patients, regardless of age, with a diagnosis of breast, rectal, pancreatic or lung cancer receiving 3D conformal radiation therapy

Denominator Criteria (Eligible Cases):

Diagnosis for breast, rectal, pancreatic or lung cancer (refer to the original measure documentation for International Classification of Diseases, Tenth Revision, Clinical Modification [ICD-10-CM] codes)

AND NOT

Diagnosis for metastatic cancer (refer to the original measure documentation for International Classification of Diseases, Tenth Revision, Clinical Modification [ICD-10-CM] codes)

AND

Patient encounter during the reporting period (refer to the original measure documentation for Current Procedural Terminology [CPT] codes)

Exclusions
None

Exclusions/Exceptions

not defined yet

Numerator Inclusions/Exclusions

Inclusions

Patients who had documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues

Note: Refer to the original measure documentation for Current Procedural Terminology (CPT) codes.

Exclusions
None

Numerator Search Strategy

Fixed time period or point in time

Data Source

Administrative clinical data

Registry data

Type of Health State

Does not apply to this measure

Instruments Used and/or Associated with the Measure

2016 Claims/Registry Individual Measure Flow, PQRS #156 NQF #0382: Oncology - Radiation Dose Limits to Normal Tissues

Computation of the Measure

Measure Specifies Disaggregation

Does not apply to this measure

Scoring

Rate/Proportion

Interpretation of Score

Desired value is a higher score

Allowance for Patient or Population Factors

not defined yet

Standard of Comparison

not defined yet

Identifying Information

Original Title

Oncology: radiation dose limits to normal tissues.

Measure Collection Name

Oncology

Submitter

American Society for Radiation Oncology - Medical Specialty Society

Developer

American Society for Radiation Oncology - Medical Specialty Society

Funding Source(s)

Unspecified

Composition of the Group that Developed the Measure

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Financial Disclosures/Other Potential Conflicts of Interest

Conflicts, if any, are disclosed in accordance with the Physician Consortium for Performance Improvement® conflict of interest policy.

Measure Initiative(s)

Physician Quality Reporting System

Adaptation

This measure was not adapted from another source.

Date of Most Current Version in NQMC

2015 Nov

Measure Maintenance

Unspecified

Date of Next Anticipated Revision

Unspecified

Measure Status

This is the current release of the measure.

This measure updates a previous version: American Society for Therapeutic Radiology and Oncology, American Society of Clinical Oncology, Physician Consortium for Performance Improvement®. Oncology physician performance measurement set. Chicago (IL): American Medical Association (AMA); 2010 Sep. 47 p. [15 references]

Measure Availability

Source not available electronically.

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NQMC Status

This NQMC summary was completed by ECRI Institute on September 8, 2008. The information was verified by the measure developer on October 16, 2008.

This NQMC summary was edited by ECRI Institute on September 28, 2009.

This NQMC summary was retrofitted into the new template on June 7, 2011.

This NQMC summary was edited by ECRI Institute on April 27, 2012.

Stewardship for this measure was transferred from the PCPI to the ASTRO. ASTRO informed NQMC that this measure was updated. This NQMC summary was updated by ECRI Institute on May 4, 2016. The information was verified by the measure developer on May 24, 2016.

Copyright Statement

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Production

Source(s)

American Society for Radiation Oncology (ASTRO). Oncology: radiation dose limits to normal tissues. Fairfax (VA): American Society for Radiation Oncology (ASTRO); 2015 Nov 17. 7 p.

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